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TUBUS WITH SEALED CUFF

Abstract:

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(54) TUBUS WITH SEALED CUFF

(57)

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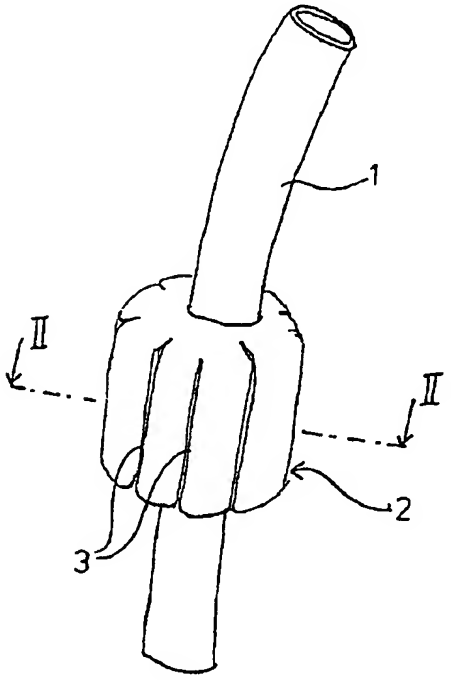

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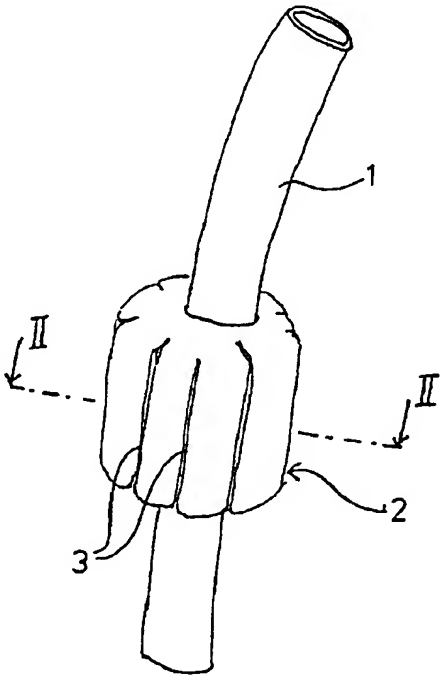

(57) Abrégé/Abstract:
The present invention relates to a tubus (1) for intubating into the trachea of a patient. Said tubus (1) comprises a central lumen (4) for ventilation or respiration and at least one inflatable cuff (2) which is provided at the outer side of the tubus (1). Said cuff (1) is used for sealing the outer side of the tubus against the wall of the trachea. The outer surface of said cuff (2) is provided with a coating (6) which is more or less free-flowing and/or can swell. The problem of the insufficient sealing is thereby resolved. The cuff (2) is not very sensitive. There is no need for particularly high swelling pressures.

ABSTRACT

The present invention relates to a tubus for intubating into the trachea of a patient. Said tubus comprises a central lumen for ventilation or respiration and at least one inflatable cuff which is provided at the outer side of the tubus. Said cuff is used for sealing the outer side of the tubus against the wall of the trachea. The outer surface of said cuff is provided with a coating which is more or less free-flowing and/or can swell. The problem of the insufficient sealing is thereby resolved. The cuff is not very sensitive. There is no need for particularly high swelling pressure.

The present invention concerns a tube for introduction into the trachea of a patient, comprising a central lumen for respiration or artificial respiration and at least one inflatable cuff which is provided at the outside of the tube and which serves to seal off the outside of the tube with respect to the wall of the trachea.

Such a tube may be a tracheotomy tube which is introduced through a trachea incision or an endotracheal tube which serves through the mouth or the nose for the purposes of artificial respiration of a patient who is under anaesthetic or in a coma.

Tubes of that kind are very frequently used in intensive care medicine. A particular problem, particularly in the case of prolonged artificial respiration by means of a corresponding tube, lies in the occurrence of pneumonia symptoms which occur comparatively frequently in the case of patients in intensive care and which are evidently in some way connected to that kind of artificial respiration.

When using a corresponding tube, as already mentioned it is introduced into the trachea of a patient and positioned in such a way that the region of the tube which at its outside is provided with the inflatable cuff is disposed in the region of the trachea and generally directly beneath the larynx. The cuff is then inflated by way of a separate hose or a line which is integrated into the wall of the tube, in which case the pressure in the cuff can certainly be some umpteens of millibars. The cuff is thereby inflated and bears with its outside wall against the inside surface of the trachea. In that way however regular transportation of secretion along the wall of the trachea (in an upward direction) is impeded and in addition secretion formation is possibly greatly stimulated by the foreign body. The secretions which are formed and which accumulate for example above the cuff in the region around the tube are very good breeding grounds for the most widely varying kinds of bacteria and other pathogens under the conditions which prevail there in respect of temperature and moisture. Admittedly, it could be thought that lung infection is nonetheless prevented because more specifically the cuff bears closely against the wall of the trachea and thus ensures that secretion which is greatly enriched with pathogens and which accumulates at the outwardly facing end of the cuff cannot penetrate into the

bronchial tubes which are disposed more deeply, but it has been found that nonetheless pneumonia frequently occurs, which is to be attributed to a considerable degree to the use of such a tube.

In particular investigations seem to demonstrate that, in spite of its flexibility and mobility and in spite of being inflated to relatively high pressures which can still be some umpteens of millibars, the cuffs nonetheless do not bear sealingly everywhere against the wall of the trachea and/or also have a tendency to form folds, in which case those folds form a passage for secretion and germs which can then result in more serious infections of the lungs.

It has already been proposed that particularly thin-wall and/or particularly elastic cuffs may be used in order to avoid the formation of such folds, but those cuffs suffer from the problem that they are relatively delicate and can be very easily damaged, in which case they then totally lose their sealing and holding function.

Alternatively it would also be possible to try to increase the pressure in those cuffs, which however under some circumstances could result in an excessive loading on the trachea, the surface cells (mucous membrane) of which can be destroyed by the high pressure to which they would then be exposed, in which case possibly even relatively deep necroses can occur with the inclusion of the annular cartilage.

In comparison with that state of the art, the object of the present invention is to provide a tube having a corresponding inflatable cuff, which eliminates the problem of inadequate sealing integrity and which nonetheless is not particularly delicate nor does it require particularly high inflation pressures.

That object is attained in that the cuff on its outer surface has a coating which is swellable and/or limitedly capable of flow.

When such a coating, after the cuff has been pumped up or inflated in the trachea of a patient, is caused to swell up, the material which has swelled up closes off any leakages which may possibly still be present. In particular the coating material which is possibly in any folds and the like also swells up so that those folds no longer form passages through which anything can move past the cuff. Even if the coating is not unreservedly swellable but at least limitedly capable of flow, a similar effect can be achieved as, more specifically at mechanically loaded locations, for example along the bend lines or the outside surfaces, which are pressed against each other, in the region of folds or the like which are formed, the coating material is displaced and is

distributed to other regions which remain free. In this case also any folds which occur are filled with the coating material so that the formation of any transport passages in the longitudinally direction of the cuffs can be prevented.

It will be appreciated that the coating material must enjoy sufficiently good adhesion to the material of the cuff in order not to be displaced from the surface which is to be sealed off into the end regions of the cuff, due to the slight pressure differences which can occur between the two ends of the cuffs in the trachea, so that the sealing function could be lost.

For the same reason the material should also not be excessively capable of flow and for example in the condition of use could be of the consistency of a gel or a cream, possibly also a very viscous oil. A preferred viscosity for the material at body temperature (37°C) is at least 10 Pas (Pascal second), preferably more than 40 Pas.

The coating material may also more or less form a unit with the material of the cuff insofar as for example the coating material partially diffuses or partially caused to diffuse into the wall of the cuff or insofar as it involves a chemical bonding to the material of the cuff. In addition thin coating layers can also be deliberately and specifically applied to the cuff material, which in turn adhere firmly to the cuff material but which at the same time also afford a good adhesion basis for the coating to form the sealing effect. The transition from the material of the cuff which is admittedly elastic but nonetheless as tear-resistant as possible and practically not capable of flow, to the coating material, can be more or less fluid, which improves the adhesion properties of the coating material to the cuff material. The coating material may also be a material in which upon normal storage at ambient temperature swelling does not occur nor is there any flow capability worth mentioning (of the order of magnitude of between 1 and 10 Pas). The swellability or flow capability can be triggered for example by moisture and heat, in particular by the moisture and temperature conditions which obtain in any case in the interior of a trachea, but equally also by reagents, catalysts, irradiation with X-ray radiation, UV-radiation, light or also ultrasound or by other mechanical treatment. In addition reagents, catalyst and irradiation procedures or mechanical treatments of the above-indicated kind can also be used for achieving good bonding of the coating to the base material of the membrane.

A preferred embodiment of the invention is one in which the coating material is swellable with water, in which case the swollen coating material may also be limitedly capable of flow. The wall of the cuff itself preferably comprises a polymer and if possible is relatively thin, that is to say the thickness of the wall should preferably be not more than 500 μm, better still not more than 200 μm and particularly preferably not more than 30 μm.

Very diverse substances fall to be considered as the coating materials, in particular mucilage substances and mucus-forming substances or gel-forming substances, as well as foam-forming substances. More particularly these can be non-ionogenic mucilage substances such as for example salep mannan, guaran, carobin, starch from wheat, corn etc, xanthan gum, chitosan, collagen, carmellose, hypromellose, macrogole etc, and equally it is also possible to consider anion-active mucus-forming agents such as for example gum arabic, tragacanth, karaya gum, pectins, alginic acid, carrageenan, agar, agarose, in particular rehydratable agarose gels, gelatine type B and carboxymethylcellulose. Cation-active mucilage substances (gelatine type A) can also be used for the coating. Mucilage substances comprising drugs such as radix althaeae, semen lini, semen psylli, semen foenugreci, semen isphaghulae, seed shells of plantago ovata, inorganic gel-forming agents and water-swellable gels comprising gel-forming agents of synthetic origin, the modification products thereof and combinations of all the above-mentioned substances can also be used. In addition polymethacrylic acid and salts thereof, polyacrylic acid and salts thereof, polydimethyl siloxane and mixtures thereof in combination with glycerine, waxes, greases or fats or Vaseline, as well as emulsifiers. A further important group of coating agents which are suitable for the present invention are polyethylene glycols.

Furthermore the coatings can comprise auxiliary substances such as association colloids (of amphiphilic, non-ionogenic, anionic or cationic nature) and/or dissolution aids (of ionogenic or non-ionogenic nature). It is also possible to provide a plurality of coatings one upon the other, which in themselves possibly do not yet have the desired sealing property but which upon mechanical loading of the double layer thoroughly mix or react with each other and thereby form a layer which has the desired properties.

In principle all water-swellable gels, natural or synthetic substances, polymers or combinations thereof can be involved. Particularly suitable materials are also

thixotropic substances, that is to say materials which change their flow characteristics under load, that is to say which when under a greater loading and when shearing forces occur are more easily capable of flow than when a lower level of loading is involved. The above-mentioned foam-forming agents can also improve the properties of the sealing layer.

In regard to the above-mentioned foam-forming agents, it should also be noted that small bubbles which are formed in a corresponding layer between the cuff and the wall of the trachea impede any fluid transport to a considerable extent. That is related to the relatively great capillary forces or surface tension values which occur at the surface of foam bubbles so that fluid secretion is bound by corresponding foam bubbles by virtue of those adhesion forces and prevent the further flow of secretion.

Particularly suitable for the coatings according to the invention are also polymer foams and in that respect in particular those foams which if possible comprise the same or a very similar basic material as the wall of the membrane itself. That provides on the one hand very good bonding of the coating comprising a foam material while on the other hand, as already mentioned, the foam layer prevents in a particularly effective manner any flow of secretion between the outside wall of the membrane and the wall of the trachea, and equally in the passages formed in folds of the membrane. In this respect in particular also open-pore foams or foam layers are highly suitable. The foam layers also have the advantageous property that they can be compressed very greatly and in that respect are highly suitable for filling the cavities which are formed in folds while the foam in some fold regions is greatly compressed and caused to collapse, it can remain expanded in regions of relatively great cross-sections which typically occur at the base of corresponding folds, and it can thus completely fill the cavity which is formed.

As an alternative to the water-swellable gels it is also possible to use hydrophobic, brushable forms of preparation of adequate viscosity, for example hydrocarbon gels such as lipogels or silicone gels, as are known as solution, suspension, emulsion or suspension-emulsion lipogels. Likewise stearate salves or creams are suitable as coatings. It is advantageous if the coating is relatively firm and less capable of flow at ambient temperature, but melts or becomes softer at body temperature.

The cuffs should as far as possible be fold-free when they are inflated and bear snugly against the wall of the trachea, in which respect in particular thin-wall cuffs are of advantage. The pressures used should be markedly less than 1 bar.

Polymer materials which have a glass transition point at a temperature above 30°C are also to be considered as coating materials.

In a further preferred embodiment of the invention it is provided that the cuff comprises an elastic material and is of such dimensions that in the non-inflated condition it bears practically without folds and relatively snugly against the outside wall of the tube while in an inflated condition under an inflation pressure of between 20 and 30 millibars it is of a diameter - to be measured perpendicularly to the axis of the tube - which is at least 50% greater than the outside diameter of the tube or the previous diameter of the cuff in the non-inflated condition, in which respect that diameter in the inflated condition can also be 100% greater.

By using a suitably elastic material which even at a relatively low inflation pressure of some umpteen millibars already experiences an increase in the radius of the cuff of 50% or more, it is possible to ensure freedom from folds for the cuff in the inflated condition as the cuff is already substantially fold-free in the non-inflated condition. That also avoids the occurrence of the above-described passages which occur in particular along folds and along which secretion can possibly pass from the region above the cuff into the region below the cuff. This embodiment could therefore under some circumstances also be used entirely without any additional coating agent on the outside surface of the cuff and nonetheless provide a tight sealing effect.

In combination with cuffs which comprise polymer material, coatings comprising water-swellable gels of gel-forming agents with non-covalent bonding of the polymer chains (in the manner of homeopolar half-valence gels, subsidiary valence gels or substances cross-linked by coulomb forces) have proven to be very suitable.

Coatings comprising water-free, brushable forms of preparation which however can absorb water in order then to swell and which for example comprise natural or synthetic substances or polymers and/or combinations thereof have also proven to be highly suitable. Another group of suitable coatings comprises hydrophobic, brushable forms of preparation of a viscosity of 2 Pas and more (for example hydrocarbon gels such as lipogels or silicone gels in the manner of solution, suspension, emulsion, or suspension-emulsion lipogels as well as stearate salves and creams).

In general terms most of the coatings in question can be classified in one of the following groups, in which respect it will be appreciated that the properties in question should be permanently retained even in the trachea.

a) The viscosity of the coating (in the condition of being introduced into the trachea and under the conditions obtaining there in respect of temperature and/or moisture) is at least 2 Pas, better still at least 10 Pas, for example 40 Pas or more;

b) the coating material has relatively great adhesion to the material of the cuff, in which respect that adhesion for example is so great that a pressure difference of for example 30 millibars at the ends of a sealing gap which is for example 200 μ in width does not result in the layer material flowing out of the gap;

c) the material is highly swellable (at least a 5-fold increase in volume); and

d) the material is applied in a foam layer (of a minimum thickness of for example 200 μ) and it can be compressed by at least a factor of 3 at low surface pressures of some umpteen millibars.

Further advantages, features and possible uses of the present invention will be clearly apparent from the description hereinafter of a preferred embodiment and the accompanying Figures in which:

Figure 1 diagrammatically shows a tube according to the invention with an inflated cuff,

Figure 2 is a view in section viewing along the axis of the tube and in a section plane which extends approximately along the dash-dotted line indicated at II-II in Figure 1, and

Figure 3 is a view on an enlarged scale of a portion corresponding to the circle identified by III in Figure 2.

Reference is made to Figure 1 showing an endotracheal or also a tracheotomy tube 1 which essentially comprises a hose or a tube 1, at the outer periphery of which an inflatable cuff 2 is provided at a central portion. The cuff 2 can possibly be fixedly welded to the hose or tube 1 but it can also be glued thereto or made in one piece with the tube 1. A passage (not visible here) which is provided in the wall of the tube 1 has an opening in the outside wall of the tube 1, in the region of the cuff 2, so that the cuff 2 can be inflated but possibly also vented by way of that outlet opening of the passage which is provided in the wall of the tube 1. Respiration or artificial respiration occurs through the central lumen 4 of the tube 1.

Figures 1 to 3 show the subject-matter of the invention in only highly diagrammatic form and also the formation of folds 3 which can be seen in all three Figures is only diagrammatically illustrated here and, as will be appreciated, the folds do not have to be of a uniform configuration which extends over the entire longitudinally extent of the cuff.

Figure 2 shows the tube in section in the region of the cuff 2. Figure 2 shows hatched the wall of the tube 1, a central lumen 4, and two passages 5 which are provided in the wall of the tube 1 and which can serve for inflating and venting purposes and also for feeding or sucking away fluid or secretion, depending on where the lower ends of the passages 5 open, which passages can open at the upper end of the tube in corresponding suction removal or flushing devices. A corresponding passage 5 also opens in the outside wall of the tube 1 in the region of the cuff 2.

In the Figures, the inflatable cuff which approximately in the illustrated condition can bear against the wall of a trachea is shown with a whole series of longitudinal folds 3. It will be appreciated that these folds 3 do not all have to extend parallel and that such folds do not necessarily have to extend over the full length of the cuff 2. On the contrary the view is only diagrammatic and is intended to show that there are some folds 3 present at all and that, by virtue of those folds 3, there can also be passages, even if of very small cross-section, along which secretion can possibly flow from the region above the cuff into the region below the cuff so that pathogens which can find advantageous conditions for growth in particular above the cuff in the secretion can penetrate into the deeper respiratory passages and can give rise to pneumonia.

In accordance with the invention that is prevented by a coating 6 on the outer surface of the cuff 2, which can be seen only in the enlarged view of Figure 3. As already mentioned, Figure 3 shows the region indicated by the circle in Figure 2, in a still further enlarged condition, in which respect in this case also the view is only diagrammatic and in particular the thickness of the coating layer 6 is possibly exaggerated in relation to the thickness of the wall of the cuff 2 which is only shown as a line, in which respect on the other hand however corresponding thickness ratios should also not be excluded.

Two folds 3 can be seen in the enlarged region in Figure 3, more specifically a somewhat less deep fold 3 on the left in Figure 3 and a comparatively deeply

extending fold 3 on the right in Figure 3. Figure 3 also indicates by hatching a coating 6 which for example comprises a water-swellable gel.

When the tube 1 together with the cuff 2 which has initially not yet been inflated and which bears firmly against the tube 1 or hangs slackly down is introduced into the trachea of a patient, the layer 6 is still very thin and can scarcely be perceived, that is to say it would be shown in the view in Figure 3 possibly only as a layer which together with the wall of the cuff 2 could only be illustrated by a slightly greater line thickness.

Upon contact occurring with the water-bearing secretion in the trachea of a patient that coating material can swell up to form a layer 6 which is shown in broken line in Figure 3. The individual folds 3 form in particular in the proximity of their bottom where the wall material of the cuff involves the greatest curvature a cavity or a passage involving the cross-section of a drop. In other words, the two mutually opposite wall portions of the cuff 3, in the region of such a fold 3 in the proximity of the bottom of such a fold, do not bear firmly and sealingly against each other, which is presumably related to the resilient return forces which act in the material of the cuff 2 and which mean that the bend at the bottom of the fold 3 cannot be of just any sharpness but is of a finite curvature which results precisely in that passage formation effect. If now however a coating is provided in that region, which swells up under the effect of moisture or for example also heat, then that passage is in fact closed by the swelling coating material 6 which can be as desired plastically deformable or also capable of flow. Moreover, as will be appreciated, the coating material 6 also swells in the regions where the wall portions of the cuff 2 bear against each other with their outside surfaces in the fold region and there possibly pushes them somewhat away from each other so that the layer material 6 is formed continuously in all folds and sealingly closes the fold passage which is possibly formed at any location. The same moreover also applies in the curve region at the transition of the outer, more or less cylindrical periphery of the cuff to one of the folds 3. There too the swelling layer 6 expands and forms a continuous homogeneous layer which is disposed between the inside surface of the trachea and the cuff material 2. A similar effect moreover is also achieved if the layer is spread thinly on the outside surface of the cuff 2, as a layer which is more or less capable of flow, in the form of a cream or a gel. The pressure which is applied by the wall portions, which bear against each other, of a fold 3

against the coating material 6 which is capable of flow provides that the coating material 6 is in part squeezed out of the fold region but in part is also urged into the bottom of the fold 3, where otherwise the above-described passages typically form. That prevents or blocks corresponding passages. The coating material is distributed at the surface between the trachea and the cuff wall 2, according to the available conditions in respect of space.

Apart from embodiments in which the coating 6 is relatively firm and in particular abrasion-resistant during storage at ambient temperature and in the dry condition and those layers only assume the desired properties in terms of being capable of flow and attaining sealing integrity by virtue of some irradiation, by means of moisture, heat, a reagent or also in conjunction with catalysts, the coatings can also permanently be of the gel-like condition in which they are capable of flow, and then for the purposes of storage and transportation they can be covered for example with a thin protective foil or protective sleeve which can extend over the cuff and possibly also accommodate the entire tube. Preferably such a sleeve or cover then comprises a material which at any event does not involve a greater adhesiveness or adhesion force in relation to the coating material than the cuff material. The latter preferably comprises a polymer material. If moreover the wall material of the cuff 2 is as thin as possible, this ensures that the passages which are possibly present, in the form of folds 3, are of a very small cross-section from the outset so that these small cross-sections can be particularly easily filled with a small amount of coating material.

CLAIMS

1. A tube for introduction into the trachea, comprising a central lumen (4) for artificial respiration and at least one inflatable cuff (2) which is provided at the outside of the tube (1) and which serves for sealing the tube (1) at its outsides in relation to the wall of the trachea, characterised in that the cuff has a coating (6) which is provided on its outer surface and which is swellable and/or limitedly capable of flow.

2. A tube according to claim 1 characterised in that the coating (6) has good adhesiveness to the surface material of the cuff (2).

3. A tube according to claim 1 or claim 2 characterised in that the material of the coating (6) is at least partially diffused into the surface of the material of the cuff or that there is a continuous transition from the material of the cuff (2) which is not capable of flow and which is preferably tear-resistant to the coating (6).

4. A tube according to one of claims 1 to 3 characterised in that the tube is of a maximum wall thickness of 500 μ, preferably 200 μ and particularly preferably 30 μ or less.

5. A tube according to claim 4 characterised in that the cuff comprises a polymer material.

6. A tube according to one of claims 1 to 5 characterised in that the coated cuff is covered with a removable protective sleeve or a protective foil which can be pulled off.

7. A tube according to one of claims 1 to 6 characterised in that upon contact with water the coating (6) swells up and/or becomes limitedly capable of flow.

8. A tube according to one of claims 1 to 6 characterised in that upon contact with a reagent which is to be additionally added or with a catalyst in the climate of the trachea the coating (6) swells up and/or becomes limitedly capable of flow.

9. A tube according to one of claims 1 to 8 characterised in that the coating has a considerably greater swellability and/or capability of flow at body temperature (about 36°C) than at ambient temperature (20°C).

10. A tube according to one of claims 1 to 9 characterised in that the material of the coating involves a chemical bond to the material of the cuff (2).

11. A tube according to one of claims 1 to 10 characterised in that the coating comprises a water-swellable gel.

12. A tube according to claim 11 characterised in that the coating contains at least one mucilage substance or mucus-forming agent which is selected from the group of non-ionogenic mucilage substances salep mannan, guaran, carobin, starch from wheat, corn etc, xanthan gum, chitosan, collagen, carmellose, hypromellose, macrogole etc), the group of anion-active mucus-forming agents (gum arabic, traganth, karaya gum, pectins, alginic acid, carrageenan, agar, agarose, in particular rehydratable agarose gels, gelatine type B, carboxymethylcellulose), of cation-active mucilage substance gelatine type A, the group of mucilage substances comprising drugs (radix althaeae, semen lini, semen psylli, semen foenugreci, semen isphaghulae, seed shells from plantago ovata) and/or the group of inorganic gel-forming agents (silicates, in particular colloidal silicic acid such as aerosil, bentonites, montmorillonite, hectorite, baydelite, elkonite, halloysite, veegum etc).

13. A tube according to one of claims 1 to 12 characterised in that the coating comprises water-swellable gels which are produced using gel-forming agents of synthetic origin, their modification products and/or combinations thereof, wherein cross-linking agents are possibly used in order for example to produce polyelectrolytes, polycarboxylic acids such as polyacrylic acid and its salts (Carpopol 904), polymethacrylic acid and its salts, polysulphonic acids, polyacrylonitriles etc,

polyhydric alcohols (polyvinyl alcohol, polyhydroxyethylmethylacrylate etc), polyethylene glycols (MW 200 - 7500), polyvinyl pyrrolidone, polyols, siloxanes such as for example polydimethylsiloxanes (Silopren U1, - U10, - U165), so-called hydrophilic polyurethanes and mixtures thereof in combination with glycerine, waxes, fats or greases or Vaseline and emulsifiers.

14. A tube according to one of claims 1 to 13 characterised in that the coating is additionally produced using auxiliary substances such as association colloids (of amphiphilic, non-ionogenic, anionic or cationic nature) and/or dissolution aids (of ionogenic or non-ionogenic nature).

15. A tube according to one of claims 1 to 12 characterised in that the coating of the cuff is produced using gel-forming agents with non-covalent bonding of the polymer chains by way of physical interactions (in the manner of homeopolar half-valence gels, secondary valence gels or substances cross-linked by Coulomb forces (salt formation).

16. A tube according to one of claims 1 to 15 characterised in that the coating contains foam-forming agents.

17. A tube according to one of claims 1 to 15 characterised in that the coating comprises a polymer foam.

18. A tube according to one of claims 1 to 17 characterised in that the coating is of a viscosity of at least 10, preferably about 40 Pascal seconds (40,000 centipoises) or more.

19. A tube according to one of claims 1 to 18 characterised in that the material of the cuff comprises a polymer which has a glass transition point at a temperature of between 20 and 40°C.

20. A tube according to one of claims 1 to 19 characterised in that the cuff comprises a sufficiently elastic material and is of such dimensions that in the non-

inflated condition it bears smoothly and fold-free against the outside of the tube and under an inflation pressure of between 20 and 30 mbar without external limitation is of a diameter which is at least 50% and preferably 100% larger than in the non-inflated condition.

21. A tube according to claim 20 characterised in that under an inflation pressure of between 20 and 30 mbar without external limitation the cuff is of a diameter of between 25 and 30 mm.

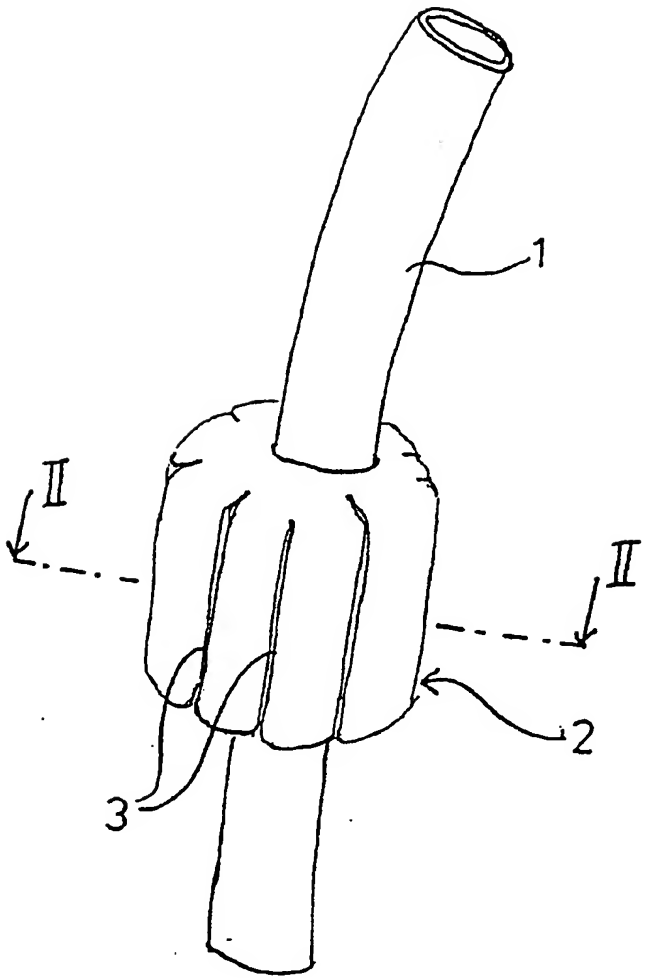

Fig. 1

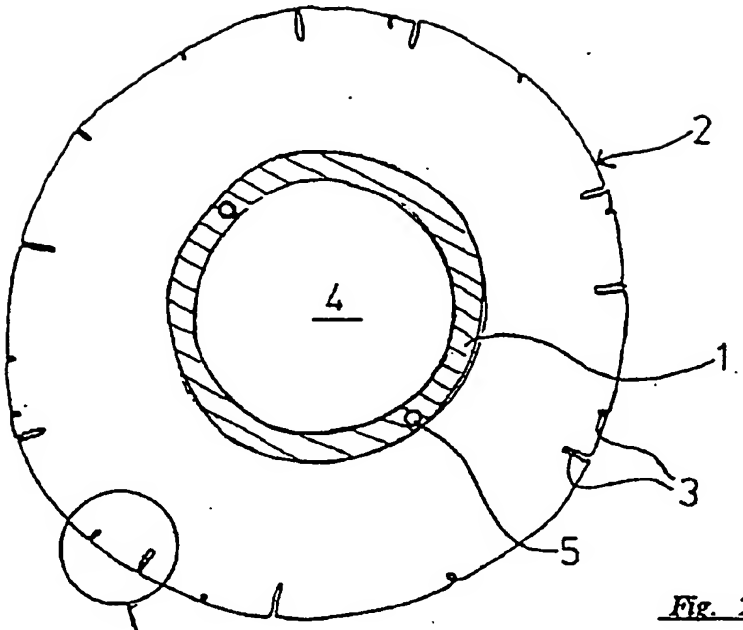

Fig. 2

Fig. 3